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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/981,506 | 10/17/2001 | Gregory R. Chiklis | 19383-014 | 6911 |
| 7590 07/14/2006 | | | | |
| Ranjana Kadle Hodgson Russ LLP One M & T Plaza Suite 2000 Buffalo, NY 14203-2391 | | EXAMINER HUMPHREY, LOUISE WANG ZHIYING | | |
| | | ART UNIT 1648 | | PAPER NUMBER |
| DATE MAILED: 07/14/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,506

Applicant(s)

CHIKLIS ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11, 13-63, 65, 66 and 68-71 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 16-48, 53-59, 62, 63, 65, 66, 68, 69 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 13-15, 49-52, 60, 61 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Final Office Action is in response to the After-Final amendment filed on 24 April 2006. Claims 1, 12, 64, and 67 are canceled. Claims 70 and 71 are newly added. Claims 2-11, 13-63, 65, 66, 68-71 are pending, of which claims 5-11, 16-48, 53-59, 62, 63, 65, 66, 68, 69, and 71 are withdrawn from consideration and claims 2-4, 13-15, 49-52, 60, 61, and 70 are under final rejection.

Response to Arguments

Claim Rejection - 35 USC § 112, 1st ¶, written description

The rejection of claims 2, 3, 12-14, 49-51, and 60 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicants' arguments that all purified microorganisms can be rendered non-pathogenic by covalent bonding of surface proteins with reactive groups and yet amenable to nucleic acid amplifications.

Claim Rejection - 35 USC § 102

The rejection of claims 2-4, 12-15, 49-52, 60, and 61 under 35 U.S.C. §102(b) as being anticipated by Davison *et al.* (1996) **is withdrawn** in view of the amendment.

New Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 2-4, 14, 15, 49-52, 60, 61, and 70 rejected under 35 U.S.C. §103(a) as being unpatentable over Shepard *et al.* (2000, April) in view of Grovit-Ferbas *et al.* (2000, July, IDS filed on 24 April 2006).

The instant invention is a composition comprising a purified nonpathogenic HIV and liquid matrix; and a kit comprising the composition.

Shepard *et al.* teaches amplification of HIV-1 RNA in blood, cerebral spinal fluid, saliva, breast milk, seminal plasma, and cervical-vaginal lavage fluid (Abstract). Shepard *et al.* does not teach purifying nonpathogenic microorganisms by covalent attachment of a compound to surface proteins.

Grovit-Ferbas *et al.* teaches chemical inactivation of HIV-1 (Abstract) in formaldehyde and virus purification by ultrafiltration (p.5803, Fractionation of virion-bound and soluble gp120 and Fractionation of virus on Percoll gradient). Grovit-Ferbas *et al.* further teaches that this inactivation method

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the virus sample of Shepard *et al.* by inactivating the virus-containing biological sample with the chemical treatment as taught by Grovit-Ferbas *et al.* The skilled artisan would have been motivated to do so to create a safe nonpathogenic positive control sample. There would have been a reasonable expectation of success, given that the chemical treatment inactivates HIV-1 by at least 7 logs and still associates with envelope through purification by ultrafiltration, as taught by Grovit-Ferbas *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Claims 2-4, 13-15, 49-52, 60, 61, and 70 rejected under 35 U.S.C. §103(a) as being unpatentable over Shepard *et al.* (2000) in view of Grovit-Ferbas *et al.* (2000), and further in view of Norman *et al.* (1970).

The instant invention is further limited to modifying the liquid matrix for lyophilization.

The relevance of Shepard *et al.* and Grovit-Ferbas *et al.* is set forth above. Neither reference teaches the preparation of the liquid matrix for lyophilization.

Norman *et al.* teaches the preservation of microorganisms by adding to the suspending fluid of sucrose a final concentration of 12% volume-by-volume (p.69, right column, line no. 8-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the virus sample of Shepard *et al.* by inactivating the virus-containing biological sample with the chemical treatment as taught by Grovit-Ferbas *et al.* and by adding sucrose as suggested by Norman *et al.* The skilled artisan would have been motivated to do so for the ease of handling and transporting lyophilized samples as well as long term storage and stability. There would have been a reasonable expectation of success, given that the sucrose-lyophilized samples enhance the recovery of freeze-dried microorganisms, as taught by Norman *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Louise Humphrey, Ph.D.
26 June 2006



JEFFREY S. PARKIN, Ph.D.
PRIMARY EXAMINER